

AD _____

Award Number: W81XWH-10-2-0112

TITLE: Mechanisms and Mitigation of Hearing Loss from Blast Injury

PRINCIPAL INVESTIGATOR: James Easter

CONTRACTING ORGANIZATION: Otologics, LLC
Boulder, CO 80301

REPORT DATE: October 2011

TYPE OF REPORT: Annual

PREPARED FOR: U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

DISTRIBUTION STATEMENT: Approved for public release; distribution unlimited

The views, opinions and/or findings contained in this report are those of the author(s) and should not be construed as an official Department of the Army position, policy or decision unless so designated by other documentation.

REPORT DOCUMENTATION PAGE				Form Approved OMB No. 0704-0188	
Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing this collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to Department of Defense, Washington Headquarters Services, Directorate for Information Operations and Reports (0704-0188), 1215 Jefferson Davis Highway, Suite 1204, Arlington, VA 22202-4302. Respondents should be aware that notwithstanding any other provision of law, no person shall be subject to any penalty for failing to comply with a collection of information if it does not display a currently valid OMB control number. PLEASE DO NOT RETURN YOUR FORM TO THE ABOVE ADDRESS.					
1. REPORT DATE (DD-MM-YYYY) 01-10-2011		2. REPORT TYPE Annual		3. DATES COVERED (From - To) 1 Oct 2010 - 30 Sep 2011	
4. TITLE AND SUBTITLE Mechanisms and Mitigation of Hearing Loss from Blast Injury				5a. CONTRACT NUMBER	
				5b. GRANT NUMBER W81XWH-10-2-0112	
				5c. PROGRAM ELEMENT NUMBER	
6. AUTHOR(S) James Easter E-Mail: easterj@otologics.com				5d. PROJECT NUMBER	
				5e. TASK NUMBER	
				5f. WORK UNIT NUMBER	
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) Otologics, LLC Boulder, CO 80301				8. PERFORMING ORGANIZATION REPORT NUMBER	
9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES) U.S. Army Medical Research and Materiel Command Fort Detrick, Maryland 21702-5012				10. SPONSOR/MONITOR'S ACRONYM(S)	
				11. SPONSOR/MONITOR'S REPORT NUMBER(S)	
12. DISTRIBUTION / AVAILABILITY STATEMENT Approved for Public Release; Distribution Unlimited					
13. SUPPLEMENTARY NOTES					
14. ABSTRACT Abstract on next page.					
15. SUBJECT TERMS Subject terms on next page.					
16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT UU	18. NUMBER OF PAGES 35	19a. NAME OF RESPONSIBLE PERSON USAMRMC
a. REPORT U	b. ABSTRACT U	c. THIS PAGE U			19b. TELEPHONE NUMBER (include area code)

14. ABSTRACT

Studies have been performed aimed at an improved biomechanical understanding of blast injury with the goal of creating new technologies for the mitigation of acoustic trauma. Fiber optic pressure sensors were used to measure pressures in cadaveric specimens during blast events. External auditory canal (EAC) pressure profiles were measured and correlated with intracranial pressure profiles. A shock tube was used to produce blast waves and response pressures measured in acoustic manikins and cadaver heads. A portable, compact system was developed to recreate observed blast pressure profiles in human temporal bones. Ossicular displacements from simulated blast events were recorded with a scanning laser Doppler vibrometer and compared with those predicted by an existing auditory injury model. Measured displacements and velocities of the ossicular chain were found to exceed predicted values for extremely high pressures and long durations characteristic of blast events. Future activities will assess the feasibility of mitigating acoustic injury in real time using an implantable system with a sensor and actuator.

15. SUBJECT TERMS

Blast injury, acoustic trauma, auditory injury, ossicular velocity, auditory damage model

16. SECURITY CLASSIFICATION OF

17. LIMITATION

18. NUMBER

19. NAME OF RESPONSIBLE

TABLE OF CONTENTS

1	SUMMARY AND OVERVIEW	1
2	INTRODUCTION	3
2.1	AIMS OF THE CURRENT EFFORT	4
2.1.1	Aim 1: Calibration of Blast Chamber with FISO Sensors	4
2.1.2	Aim 2: Correlation of EAC and Intracranial Pressure Profiles in a Blast Chamber	4
2.1.3	Aim 3: Development of a Compact, Programmable Bench Top Blast Simulator	4
2.1.4	Aim 4: Ossicular Displacements with Scanning LDV	4
2.1.5	Aim 5: Recalibration of High Intensity Blast Chamber	4
2.1.6	Aim 6: Bench Top Blast Simulator Modifications for Low Frequencies	4
3	METHODS	5
3.1	CALIBRATION OF BLAST CHAMBER WITH FIBER OPTIC PRESSURE SENSORS	5
3.2	MEASUREMENT OF EAC AND INTRACRANIAL PRESSURE PROFILES AT BLAST CHAMBER	6
3.2.1	Cadaveric specimen methods:	6
3.2.2	“Eddi” acoustic manikin head model methods:	7
3.3	BENCH TOP BLAST SIMULATION AND OSSICULAR DISPLACEMENT MEASUREMENT WITH SCANNING LDV	8
3.3.1	First Version of Bench Top Blast simulator:	8
3.3.2	Temporal Bone Preparation and Scanning LDV Recordings:	8
3.3.3	Analysis of scanning LDV data:	10
3.3.4	AHAAH model analysis and verification of scanning LDV displacements:	10
3.4	CALIBRATION OF HIGH INTENSITY BLAST CHAMBER	11
3.5	MODIFICATIONS TO BLAST SIMULATOR AND MEASUREMENT OF OSSICULAR DISPLACEMENTS AT LOW FREQUENCIES AND AT HIGH SOUND PRESSURE LEVELS:	12
3.5.1	Temporal Bone Preparation and Single axis LDV Recordings:	13
3.5.2	Data Analysis from temporal bones:	14
4	RESULTS	14
4.1	NMCSD BLAST TUBE CALIBRATION WITH FISO PRESSURE SENSORS	14
4.2	EAC PRESSURE PROFILE IN CADAVERIC SPECIMENS:	15
4.2.1	“Eddi” acoustic manikin head model pressure profiles:	17
4.3	OSSICULAR MOTIONS RECORDED WITH SCANNING LDV IN FREQUENCY DOMAIN:	18
4.4	VERIFICATION OF CURRENT AUDITORY INJURY MODELS SUCH AS AHAAH WITH PRESENT DATA:	21
4.4.1	Auditory risk units (A.R.U.) prediction from AHAAH model:	22
4.5	ARA BLAST CHAMBER CALIBRATION AND EFFECT OF PROTECTIVE EQUIPMENT:	23
4.6	OSSICULAR DISPLACEMENT AT LOW FREQUENCIES (<100 Hz) AT HIGH SOUND PRESSURE LEVELS:	25
5	KEY RESEARCH ACCOMPLISHMENTS	28
6	REPORTABLE OUTCOMES	29
6.1	ORAL PRESENTATION AT ATACCC 2011	29
6.2	POSTER PRESENTATION SELECTION FOR ARO 2012 CONFERENCE	29
7	CONCLUSIONS	30
8	REFERENCES	31

1 SUMMARY AND OVERVIEW

Objectives:

This project is directed toward an improved biomechanical understanding of blast injury with the goal of creating new technologies for the mitigation of acoustic trauma. The first research objective is to assess the applicability of fiber optic sensors to record pressures in cadaveric specimens during blast events. The second objective is to measure external auditory canal (EAC) pressure profiles and correlate these with intracranial pressure profiles. The third objective is to develop a feasible system to recreate observed pressure profiles in a compact system suitable for use in human temporal bones, and to record ossicular displacements resulting from simulated blast events. The fourth objective is to compare measured ossicular displacements with those predicted by existing auditory injury prediction models and to improve the scope and accuracy of those models. The fifth objective is to establish a quantitative understanding of the displacements and velocities of the ossicular chain, and the induced pressures within the cochlea, resulting from acoustic events known to cause hearing loss. The sixth objective is to assess the feasibility of counteracting the process of acoustic injury in real time using an implantable system with a sensor and actuator.

Materials and Methods:

Fiber optic sensors FOP-M-BA (~0.8 mm diameter, **FISO**, Quebec, Canada) were used along with more standard Dytran-2300 V (~5.5 mm diameter, DYTRAN Instruments Inc., 21592 Marilla St., Chatsworth, CA) and Endevco 8510C-50, (~3.8 mm diameter, Endevco Corporation, 888. ENDEVCO, 30700 Rancho Viejo Rd., San Juan Capistrano, CA) pressure sensors for calibrating and recording the pressure profiles. After calibration, these fiber optic pressure sensors were placed into human cadaveric heads in five locations: vertex, occiput, middle cranial fossa, middle ear cavity, and distal EAC, with a reference probe external to the head to sense the incident wave. After placement of the fiber optic sensors, two cadaveric specimens were exposed to blast events at the Naval Medical Center San Diego (NMCS D) blast lab. Blast overpressures were generated by a triggered diaphragm-rupture system creating a Friedlander waveform at the termination of a condensing tube. The digital recordings of these blast events were used to create a representative waveform for use in bench top simulations.

A compact, portable system was desired to replicate the blast event for use with human temporal bones. A speaker capable of large volume displacement was chosen and a converging cone designed to concentrate the acoustic energy and deliver it to the EAC using an aural speculum. Calibrated stimuli of either the digitized blast waveform or a harmonic chirp were presented from 85 dB SPL (0.000051 psi) to 135 dB SPL (0.0163 psi) in the first experimental setup and 80 dB SPL (0.000029 psi) to 160 dB SPL (0.2893 psi) in the second experimental setup. The energy density of the blast pressure waveform peaked at about 22 Hz. The harmonic stimuli were presented with discrete peaks from 22 Hz to 1300 Hz (22, 40, 60, 80, 100, 125, 150, 200, 250, 431, 613 and 1300 Hz).

Nine human cadaveric temporal bones were prepared by mastoidectomy and extended facial recess exposing the malleus head (M), incus body (I), incus long process (ILP), stapes superstructure (S) and round window membrane (RWM). A scanning LDV was used to obtain real-time images of the ossicles and round window membrane during harmonic and blast wave stimulation. Following

the initial experiment with the scanning LDV, a second series of experiments used a single axis LDV to measure stapedial and round window displacement specifically. Ossicular displacement was analyzed in the frequency domain. Peak displacements were averaged across bones; mean and standard errors are presented.

Results:

The fiber optic sensors (FOP-M, FISO) were cross-calibrated with electromechanical pressure sensors and found to yield consistently similar results. A Student t-test applied to the data revealed no significant difference ($p=0.345$) between waveforms recorded with both sensors during different blast triggering events.

Peak pressure within the ear canal was approximately 0.49 psi with the blast wave impinging frontally and 1.19 psi with the blast wave impinging laterally. Peak positive overpressure is approximately 0.90 psi (170 dB SPL equivalent) at the surface of the specimen.

Peak intensities produced by the original construction of the temporal bone simulator were 135 dB SPL; following modification peak intensities have been produced to 160 dB SPL with frequencies as low as 22 Hz. The observed out-of-plane peak displacements for 115 dB SPL for M, I, ILP, S and RWM are 1.62 (± 0.80), 1.53 (± 0.64), 0.48 (± 0.22), 0.29 (± 0.14), and 0.59 (± 0.17) μm respectively for harmonic stimuli ($n=5$) at 250 Hz and 12.96 (± 0.76), 8.34 (± 0.61), 7.37 (± 0.86), 7.56 (± 1.16), and 8.92 (± 2.24) μm for impulse stimuli ($n=10$) at 22 Hz. The phase difference between stapes and round window was observed to be approximately 180°.

Conclusion: Peak stapedial displacements from harmonic stimuli are similar to data reported in the literature. In general, impulse stimuli caused higher peak displacements than harmonic stimuli at similar peak sound pressure levels. Further experimentation and analysis is necessary to determine the effects of increasing intensity and to more closely match our delivered stimuli to the recorded blast events. The displacements and phase relationships observed under these conditions will be used to refine models of acoustic trauma from blast. The blast simulator system used here is a useful tool for the measurement of ossicular displacement measurements under extreme conditions. Future experiments will include modifications to the blast simulator and measurements of ossicular displacements with a single-axis LDV at sound pressure levels approaching and exceeding the levels at which rupture of the tympanic membrane is likely.

2 INTRODUCTION

The ear is the most sensitive organ to blast injury as it is specifically designed to receive and translate small changes in air pressure for hearing sensation during communication. Blast injury remains the leading cause of morbidity and mortality in both Operation Enduring Freedom (OEF) and Operation Iraqi Freedom (OIF), with 71% of returning soldiers reporting exposure to loud noises, and 15.6% reporting ringing in the ears.

The most severe cases of acoustic trauma from blast events include both a sensorineural and a conductive component. A pattern of mixed hearing loss, with incomplete spontaneous recovery of the sensorineural component, and a conductive component amenable to surgical restoration, is typical of acoustic injury from blast overpressure. Diagnoses range from eardrum perforation to H-3 or H-4 hearing profiles likely to be disqualifying from duty.

In a modern non-linear combat environment interpersonal communication and sensory awareness are essential to survival and mission effectiveness. Field testing of both passive and active hearing protective devices in various combat environments has demonstrated a defined need for both a durable and adaptive means of interpersonal communication. Dismounted soldiers cannot predict when a blast or noise exposure will occur and fixed attenuation of auditory perception reduces a soldier's sensory orientation and increases response time to an audible threat.

The immediate impact to the soldier following blast exposure is disorientation and temporary loss of hearing lasting minutes to hours and severely reducing a soldier's combat effectiveness and survivability. The long term detriments to the soldier and his unit are degraded performance due to impaired interpersonal communication, diminished sensory awareness, and potential medical disqualification from duty.

Physiology of acoustic blast injury:

Blast injury to the auditory system is caused by an intense air pressure wave (shockwave) emitted by an explosive device or high energy impact. Blast waves travel at speeds greater than the speed of sound and have an associated gas flow. The damaging energy of a blast wave is best estimated by its peak overpressure, the duration of its positive pressure wave, and the rise time of the wave to its peak pressure. Damage inflicted to the auditory system is predicted by proximity to the blast, magnitude of the blast, the orientation of the ear to the site of the explosion, and the environment within which the blast occurs. Severe auditory damage may be caused by an exposure of less than one second to a single blast wave. Those characteristics unique to blast waves predict the pattern of auditory injury resulting from blast exposure and distinguish it from noise-induced hearing loss (NIHL).

Substantial basic science and occupational health investigative energy has been directed toward defining the pathophysiology of NIHL. This has led to multiple and varied hearing protective devices, medical interventions, and work environment engineering targeted at a known pathologic process. NIHL produces cochlear injury through accumulated energy transfer.

Longer and louder noise exposure predicts a more severe hearing loss. For days following noise exposure hair cell loss continues, and this provides a time period for potential intervention with medications and auditory rest. Our project will explore the basic science of how blast energy damages the hearing structures and what will be the best way to provide protection without causing problems with interpersonal communication.

2.1 Aims of the Current Effort

Research described in this Annual Report has been organized around the following aims:

2.1.1 Aim 1: Calibration of Blast Chamber with FISO Sensors

The aim of these experiments is to calibrate the blast chamber with fiber optic pressure sensors (FISO, Inc.). These sensors are smaller than electromechanical sensors, making them well suited to cadaveric and temporal bone experimental applications.

2.1.2 Aim 2: Correlation of EAC and Intracranial Pressure Profiles in a Blast Chamber

The aim of these experiments is to correlate free-field pressures, intracranial pressures and pressures in the external auditory canal (EAC) in whole head cadaveric specimens during a simulated blast event in a shock tube at NMCSO. Initial experiments aimed at understanding dynamic and static pressure waveforms in the EAC during blast events were conducted with an "Eddi" acoustic manikin head.

2.1.3 Aim 3: Development of a Compact, Programmable Bench Top Blast Simulator

The aim of these experiments is to demonstrate a compact bench top blast simulator system suitable for use in human temporal bones, and to record ossicular displacements resulting from simulated blast events. The system developed for these experiments produces consistent pressure profiles similar to those recorded with the shock tube. It is programmable to present any desired waveform, and can be used in any facility.

2.1.4 Aim 4: Ossicular Displacements with Scanning LDV

The aim of these experiments is to measure in-plane displacements of all three auditory ossicles in response to a range of stimuli using a scanning LDV. The measured stapedial displacements in response to harmonic and impulse stimuli were compared to the predictions of a widely used auditory damage model, the Auditory Hazard Assessment Algorithm for Humans (AHAH).

2.1.5 Aim 5: Recalibration of High Intensity Blast Chamber

The aim of these experiments is to recalibrate a large (18" diameter) shock tube for intracranial pressure measurement and to develop more detailed spatial mapping and real-time pressure profiles of blast events as produced by the shock tube in proximity to the head and ear.

2.1.6 Aim 6: Bench Top Blast Simulator Modifications for Low Frequencies

The aim of these experiments is to modify the blast simulator to develop very high sound pressure levels (> 150 dB SPL) at low frequencies / long durations (< 50 Hz / > 20 msec.) with better coupling to the EAC in temporal bones. With these modifications, it is possible to measure ossicular displacements at the very high sound pressure levels and low frequency characteristic of blast, measurements absent from the current technical literature. This current set of modifications to the stimulator affords a feasible model for measuring displacements at frequencies below 100 Hz. The stimulator is adaptable to measuring displacements with varying types of blast or other potentially damaging auditory events faced by soldiers.

3 METHODS

3.1 Calibration of Blast Chamber with Fiber Optic Pressure Sensors

These experiments were conducted at NMCSO's blast overpressure (BOP) lab. The fiber optic sensor (FISO, FOP-M-BA) (as shown in Figure 1) was placed along with the Dytran 2300V sensor on an aluminum bar. The metal bar was firmly fixed inside and across the 12 inch diameter of the BOP tube perpendicular to the shock wave front. In Figure 2, the experimental setup shows both the sensors aligned side by side (1 cm apart) on the metal bar in the open BOP tube. Shock waves were created by a triggered burst of polyester film (4 mm thickness) at pressures ranging from 5 to 15 psi. This created a shock wave event with a Friedlander waveform characterized by a rapidly rising overpressure peak (time to peak less than 100 microseconds) followed by decay and an underpressure wave. NMCSO's shock tube consists of a charging compression chamber mated to a tube sealed by a rupture diaphragm. When the selected trigger pressure is reached, an initiator punctures the diaphragm, releasing a shock wave into a series of connected steel condensing tubes. The reference incident pressure is measured at a point 10 feet from the burst aperture. The BOP was repeated at constant trigger pressures and repeatability was confirmed. The FISO sensor was connected to Veloce 50 signal conditioners (FISO Inc) and analog output was recorded. Pressure measurements from Dytran and FISO sensors were recorded by a Pacific instruments data acquisition system (Pacific Instruments model 6000H, Concord, CA) at 100 kHz (10 μ S resolution) sample rate.

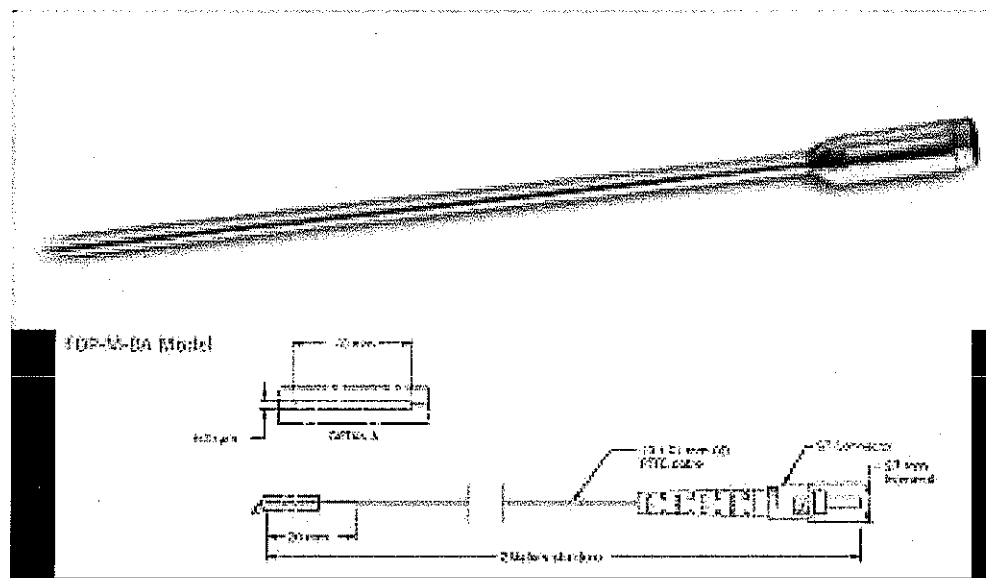


Figure 1: The FOP-M-BA model of the FISO sensor used in the current experiments.

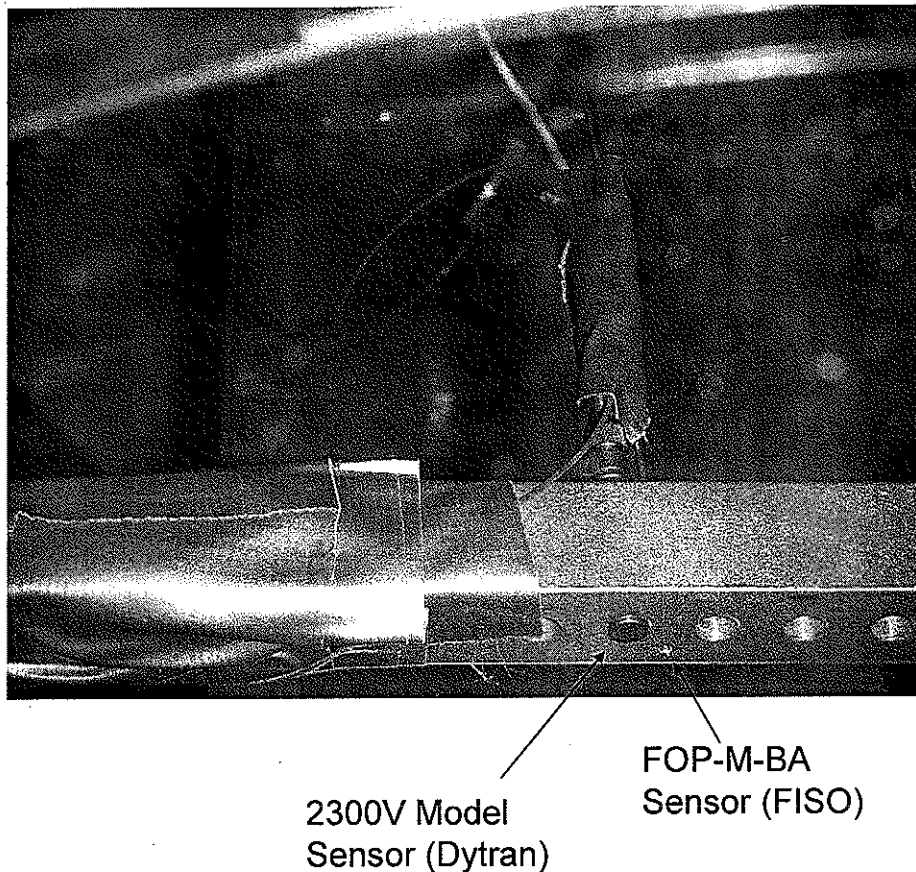


Figure 2: Side by side placement of both pressure sensors for cross-calibration.

3.2 Measurement of EAC and Intracranial Pressure Profiles at Blast Chamber

3.2.1 Cadaveric specimen methods:

Human cadaver heads were instrumented with electromechanical and fiber-optical pressure probes at selected locations within the cranium (vertex, occiput, and middle cranial fossa), the middle ear cavity and the external auditory canal. Figure 3 shows the specific location of sensors on the cadaveric specimen. Small 1-2 inch stainless steel probes of 1.2 mm inside diameter were used to locate and protect the sensors. These were installed one day before the experiment via limited craniotomies and a mastoidectomy securing the probe guides with dental cement. Fiber optic pressure sensor placement was then completed on the day of the experiment by guiding the probes to pre-set distances and securing the leads to the probe guides. The specimens were exposed to blast-overpressure events to obtain real-time correlated pressure profiles at the instrumented locations. The specimens were exposed in two different directions i.e., blast impinging frontally and laterally. The specimens were placed 30 cm from the opening of the blast tube. Figure 4 A-B shows the orientation of the cadaveric specimen during the experiment. Blast overpressure was generated by a diaphragm-rupture system creating a Friedlander waveform at the termination of a condensing tube. For this experimental sequence, the peak

positive overpressure was approximately 0.90 psi (170 dB SPL equivalent) at the surface of the specimen.

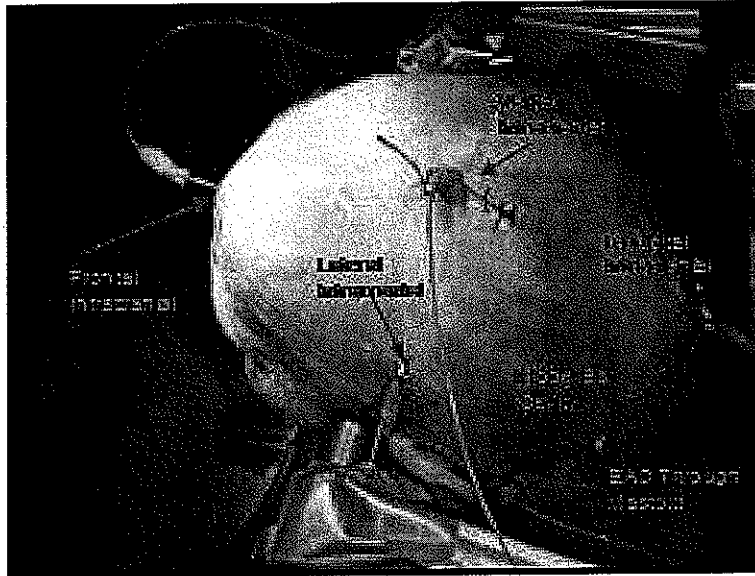


Figure 3: Cadaveric specimen with location of fiber optic probes.

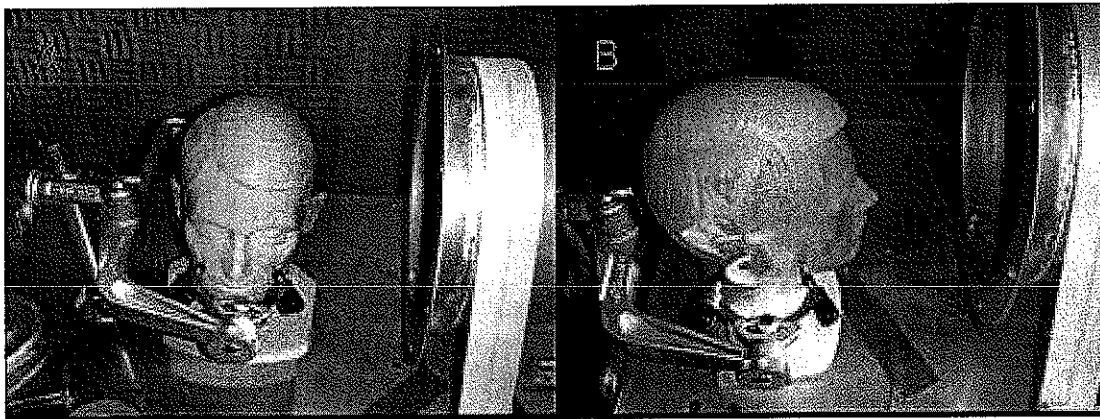


Figure 4: Experimental method with cadaveric specimen (“Eddi” acoustic manikin head is used here for illustration) placement in front of blast tube. A: Specimen facing blast event laterally. B: Specimen facing blast event frontally.

3.2.2 “Eddi” acoustic manikin head model methods:

An “Eddi” acoustic manikin head was used to study the dynamic and static pressures in the EAC during blast wave event when the specimen was exposed laterally (EAC facing blast) to blast event. Two fiber optic pressure probes (FISO-FOP-M) were placed in the EAC at orthogonal

angles. One probe was placed through an aperture in the manikin's internal space parallel to the EAC axis and another probe was placed through the manikin at the location of the mastoid bone normal to the EAC axis. Figure 5 A-B shows the exposure of "Eddi" to the blast event in lateral and frontal orientations, and Figure 5 C shows the exact locations and directions of probes.

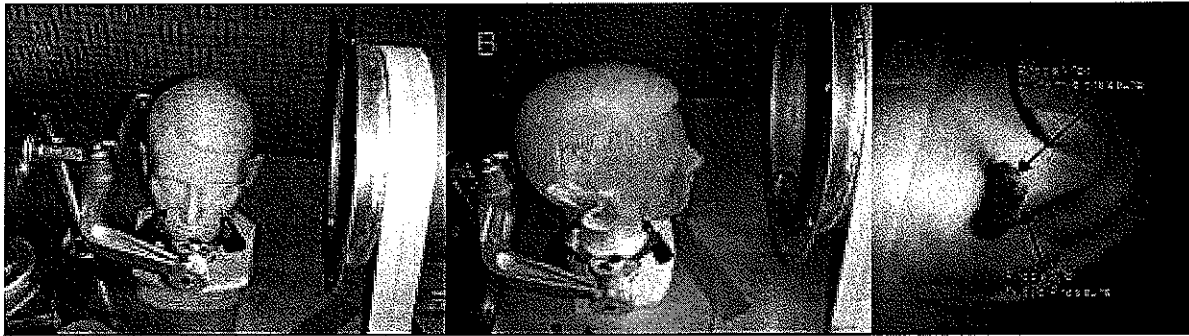


Figure 5A-B: "Eddi" acoustic manikin head with fiber optic probes. Two probes are placed in EAC and exposed to blast event laterally (A) and frontally (B). Figure 5C: Exact location of two fiber optic probes in EAC.

3.3 Bench Top Blast Simulation and Ossicular Displacement Measurement with Scanning LDV

3.3.1 First Version of Bench Top Blast simulator:

A method for producing a limited blast overpressure to the EAC or auricle was sought to allow detailed analysis of ossicular and inner ear fluid motion in response to a blast event.. The approach included studying the acoustic properties of the ear canal, generating a custom built low frequency response speaker with high volume of air movement, building a condensing cone to shape the produced wave and a polyethylene tube to transmit the wave into the EAC. A 12 inch subwoofer was fixed in a box and a condensing cone going from a 12 inch base to 0.5 inch tip was fixed on top of the subwoofer. The cone was placed inside a cylindrical tube and filled with small sand weights to reduce vibrational interference. This approach is broadly similar to that employed by the high intensity closed field speakers from TDT (TDT Alchua, FL, USA, <http://www.tdt.com/products/MF1.htm>). However, it extends the capability of the speaker to higher pressures and longer pulse durations than were previously achievable.

3.3.2 Temporal Bone Preparation and Scanning LDV Recordings:

Human cadaveric temporal bones were prepared by mastoidectomy and extended facial recess exposing the malleus head (M), incus body (I), incus long process (ILP), stapes superstructure (S) and round window membrane (RWM). The temporal bones were fixed firmly on to a vacuum vise and placed on the experimental table. The EAC was sealed by a foam plug and a polyethylene tube was used to deliver either a simulated blast impulse or high intensity harmonic stimulus to the closed canal. A probe tube microphone was used to verify the delivered stimulus level near (~ 1mm) the tympanic membrane. Figure 6A-B shows the setup of the bench top blast simulator along with scanning LDV for recording velocities. Figure 7A shows the ossicular

view of the temporal bone through scanning LDV. The scanning points were chosen to record independently the velocities of the visualized portions of: malleus head, incus body, incus long process, stapes superstructure and the round window. The stimulus was presented 3 times at every scanning point and averaged. The stimulus presentation and data acquisition was done at 125 k sampling rate and recorded and stored on the scanning LDV PC.

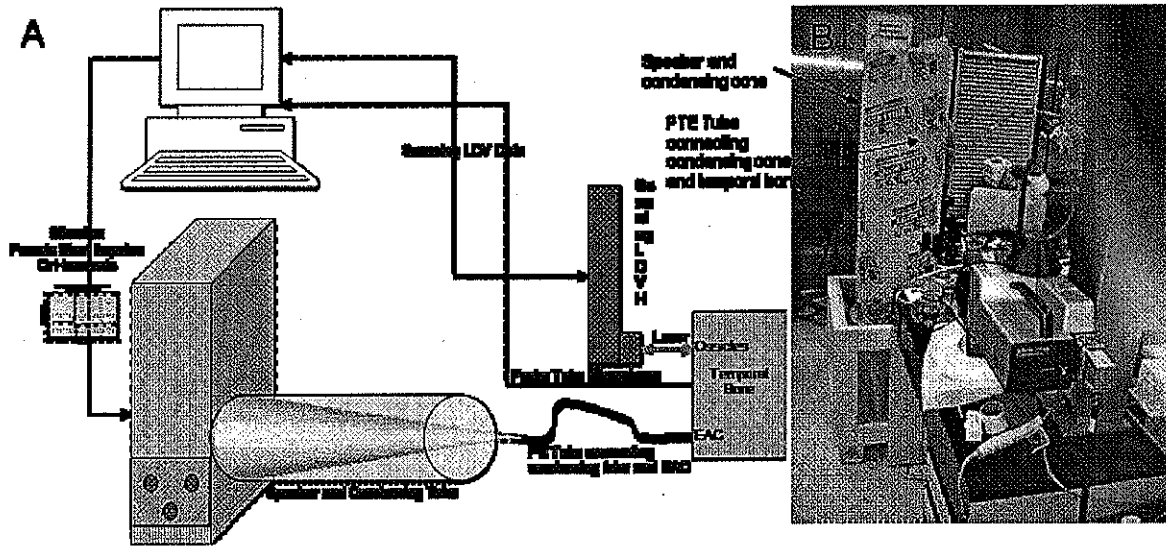


Figure 6A: The experimental setup used for scanning LDV measurement of ossicular velocities. B: Shows the actual setup image.

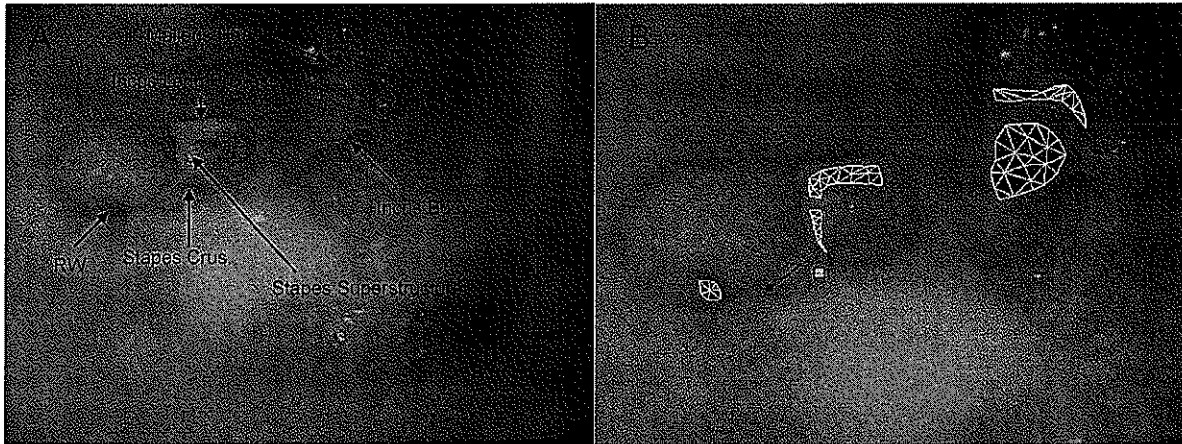


Figure 7A: The ossicular chain as seen by the scanning LDV. Different structures are marked. Figure 7B: Scanning points are selected on different structures and grouped together as wire mesh structures for visualization and analysis.

3.3.3 Analysis of scanning LDV data:

FFTs were performed and peak displacements were taken for different ossicular structures. The frequencies studied were 22 Hz for digitized blast impulse stimulus and 81, 250, 431, 613 and 1300 Hz for harmonic stimulus. A linear curve was fitted to data points across temporal bones for peak displacement versus sound level in Pascals. Curve fitting was performed for each frequency and each ossicular structure. For stapedial displacements, the time domain peak displacements and peak sound level in Pascals were also calculated.

3.3.4 AHAH model analysis and verification of scanning LDV displacements:

The stimulus waveforms at the TM were presented to the AHAH model and peak stapes displacements as predicted by the model were compared to those measured in the time domain by the scanning LDV. The AHAH model was downloaded from the website <http://www.arl.army.mil/www/default.cfm?page=343>. Figure 8 shows the output of the AHAH model.

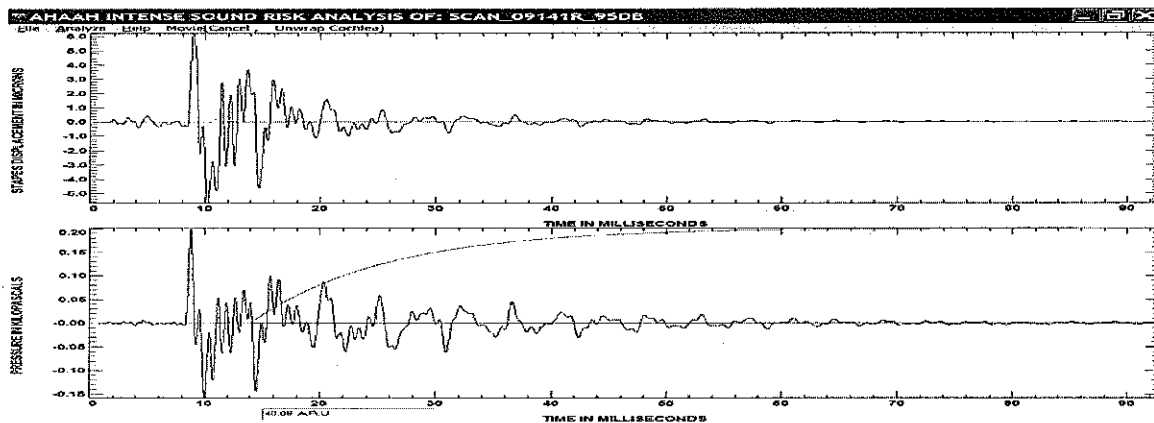


Figure 8: Screen shot showing the application of AHAAH model and estimation of stapes displacement.

3.4 Calibration of High Intensity Blast Chamber

The facility containing NMCS D's blast tube has been closed for maintenance, and the blast tube itself has not been continuously available to the research team. For this reason, and in order to improve the efficiency of the research effort, alternate shock tube facilities have been explored. One such facility is located at Applied Research Associates (ARA, Littleton, CO). This shock tube has been used to generate blast events, and results compared with those of earlier experiments. This blast chamber is similar to NMCS D's blast tube, but is larger and capable of generating more intense events. The larger shock tube and cone allow the blast waveform to more closely approach the free-field condition, in which blast air wraps around the specimen. The pressure sensors were mounted on two acoustic manikins: the "Hybrid 3" head and the "Eddi" dummy head described earlier. Sensors were placed in both models in the EAC, near the location of the TM. Sensors were also placed on both sides, front, back and crown to record the incident wave. The Endevco as well as FISO fiber optic sensors were used. A sensor was also placed in the shock tube a short distance from the head model as a reference. The experiments were conducted with each model facing the blast event and with each model's right ear facing the blast event. Measurements were made in each orientation under three conditions: unprotected, with ear muffs, and with helmet. Figure 9 shows the different approaches. Note the large diameter of the expansion cone; this permits a good approximation of the free-field blast wave in these experiments.

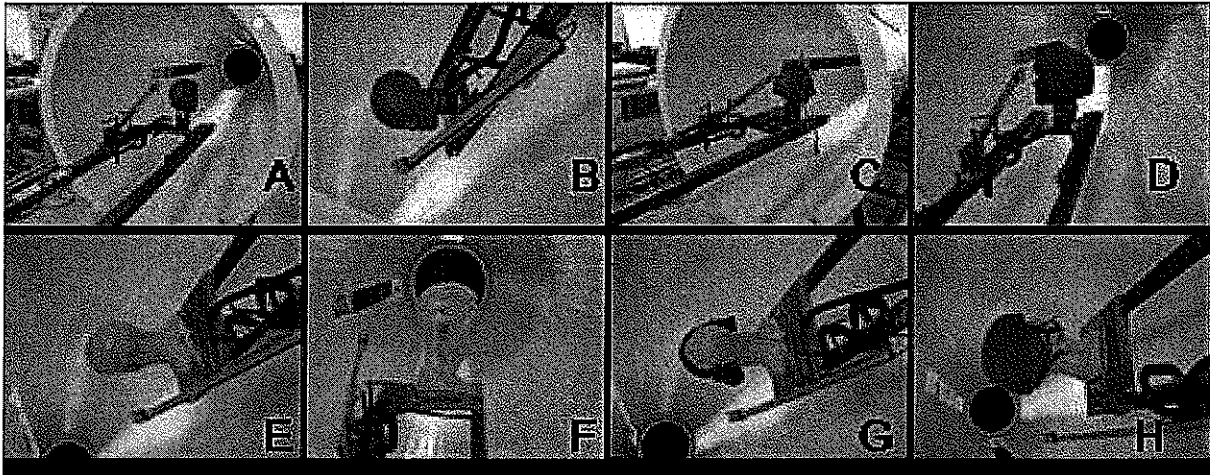


Figure 9: Different orientations and conditions for experiments at ARA's shock tube.

3.5 Modifications to Blast simulator and measurement of Ossicular Displacements at Low Frequencies and at High Sound Pressure Levels:

The results of experiments with the blast simulator system (section 2.3.1) revealed much of the ear's nonlinear response to high-intensity impulse. However, peak pressures developed by the system did not reach the desired levels – that is, pressures exceeding 150 dB SPL equivalent, characteristic of real-world blast exposure. From comparison of pressure measurements taken within the concentrator cone and in the EAC, it is believed that the primary limiting factors were deformation of the cone and attenuation of the pressure pulse by the flexible tube used to deliver the pulse to the ear. In order to improve performance, the blast simulator was modified.

The elastomer cone was exchanged for a rigid cone of similar dimensions.

The polyethylene tube connecting the end of the cone to the ear canal was entirely eliminated. Instead, the concentrator profile was continued by means of a mating cone and an aluminum aural speculum attached to the EAC. Figure 10A-B shows the current approach. This setup posed two challenges: The temporal bone must be held securely while positioned and oriented so as to mate with the rigid concentrator assembly, requiring some attention to fixturing. Also, the included angle between the EAC axis and the line-of-sight to the ossicles is narrow, forcing the LDV head to be mounted immediately adjacent to the concentrator and carefully isolated from vibration. With these problems overcome, the modified blast simulator performed beyond expectations, delivering peak pressures at and above 155 dB SPL equivalent, over durations exceeding 50 msec.

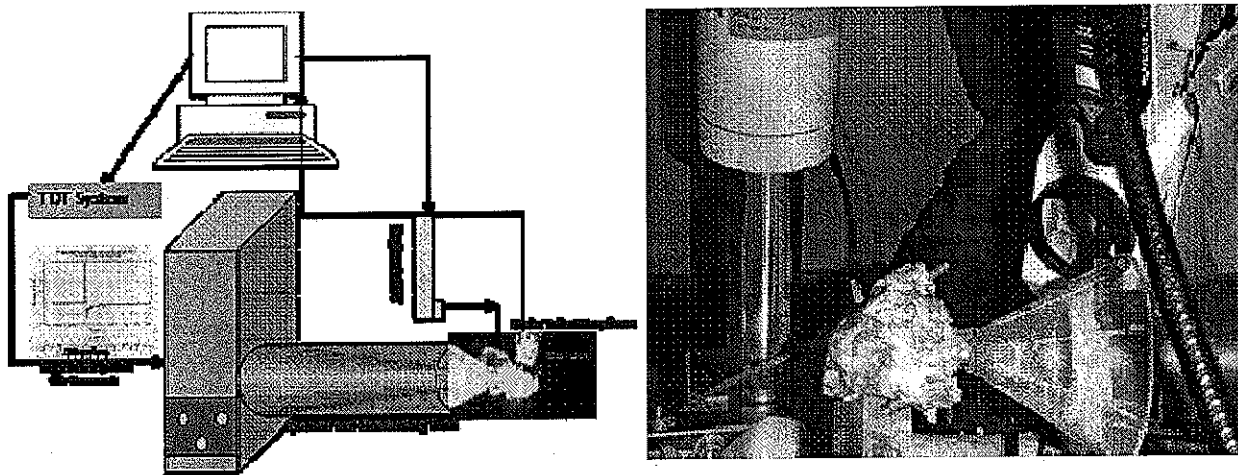


Figure 10A: The experimental setup used for scanning LDV measurement of ossicular velocities. B: Modified blast simulator setup with (L to R): temporal bone, speculum, mating cone and rigid concentrator. Note the narrow included angle between the concentrator and LDV head (in background).

3.5.1 Temporal Bone Preparation and Single axis LDV Recordings:

Human cadaveric temporal bones were prepared by mastoidectomy and extended facial recess exposing the malleus head (M), incus body (I), incus long process (ILP), stapes superstructure (S) and round window membrane (RWM) similarly to the approach discussed in section 2.3.2. Figure 10C shows the measurement points on ossicular pathway in one representative temporal bone. The temporal bones were fixed firmly to a stereotaxic table fixed to the surgical table. This approach allows the temporal bone to be adjusted in 3 axes of movement and mated to the concentrator assembly of the blast simulator. The ear speculum end of the cone placed in the ear canal was isolated with foam to limit vibration transmission. The TDT System-3 hardware connected to a PC was used to present stimulus and record LDV velocity as well as sound pressure level at the TM using B&K microphones. Glass microsphere-coated mirrors of less than 1 mm were placed on the ILP, ISJ (incudo stapedial joint) and incus body. Stimuli were presented from 80 to 160 dB SPL in 10 dB steps, presented 6 times and averaged, thus increasing signal to noise ratio. Tones at 22, 40, 60, 80, 100, 125, 150, 200, 250, 431, 613 and 1300 Hz along with an impulse blast waveform were presented for displacement measurements.

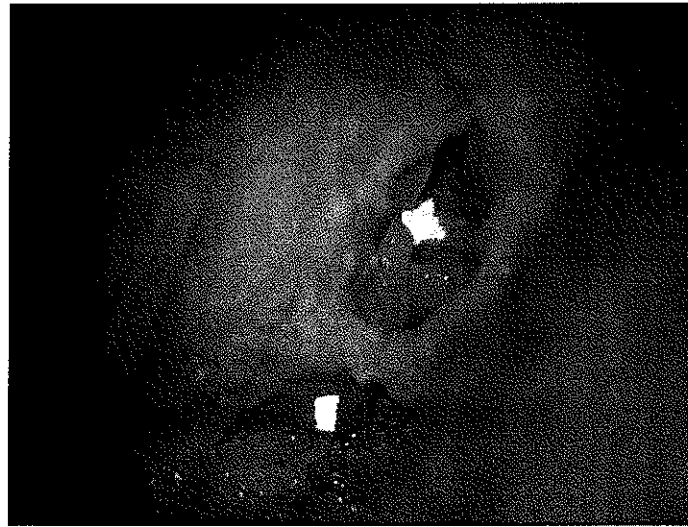


Figure 10C: Glass microsphere-coated reflectors at incus body and ISJ on a representative temporal bone. The reflective mirrors were also positioned at ILP and Incus body on another temporal bone.

3.5.2 Data Analysis from temporal bones:

LDV velocities were converted to displacements in the frequency domain for simple tones as well as digitized blast waveform.

4 RESULTS

4.1 NMCSDB Blast Tube Calibration with FISO pressure sensors

Both sensors recorded Friedlander type blast wave events. Figure 11 shows a representative blast wave event recorded at a 10 psi triggered BOP. Both sensors demonstrate similar waveforms with overpressure and underpressure waveforms. Equivalent results for both sensors were observed at 5, 7, and 15 psi triggered blast events (not shown here). A Student t-test revealed no significant ($p=0.345$) difference between waveforms recorded with either FISO fiber optic or Dytran sensors during different blast triggering events. This statistical test was performed on whole data recordings comparing the whole waveform. The data was smoothed with 25 point (250 μ S) using Matlab (v7.1, The MathWorks Inc, Natick, MA) and maximum (overpressure) and minimum (underpressure) peaks were noted. Figure 12 shows the maximum and minimum peaks respectively in panels A and panels B for both sensors. The Dytran and FISO sensors peaks and minimums showed no significant difference ($p=0.533$) for $n=11$ blast events recorded. The current results shows the repeatability of using small FISO sensors and shown to be providing consistent pressure recordings similar to other large pressure sensors.

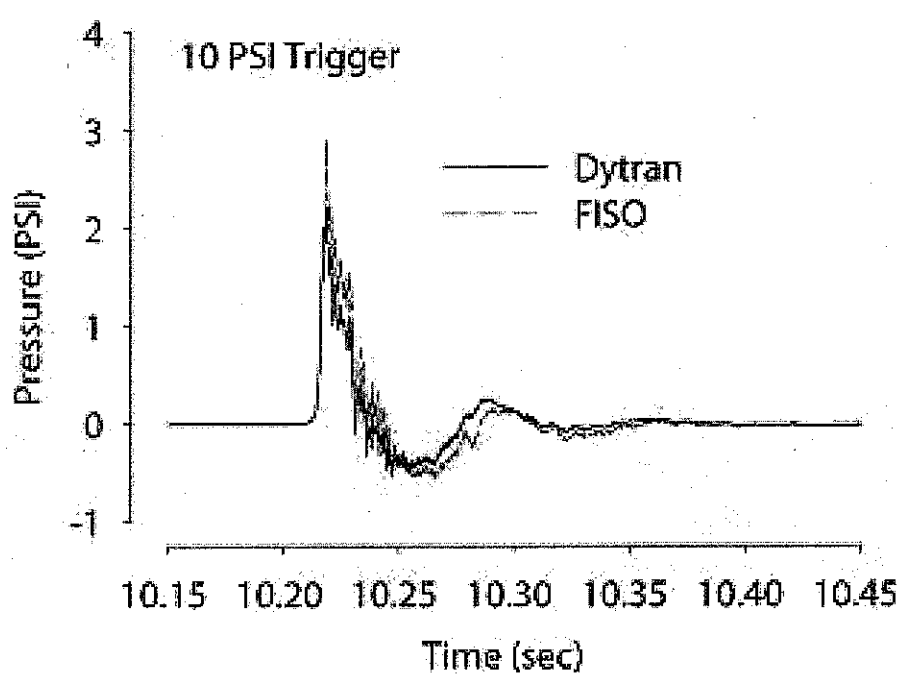


Figure 11: Blast event recorded for 10 psi trigger event with both sensors. The student t-test revealed no significant ($p=0.345$) difference across waveforms.

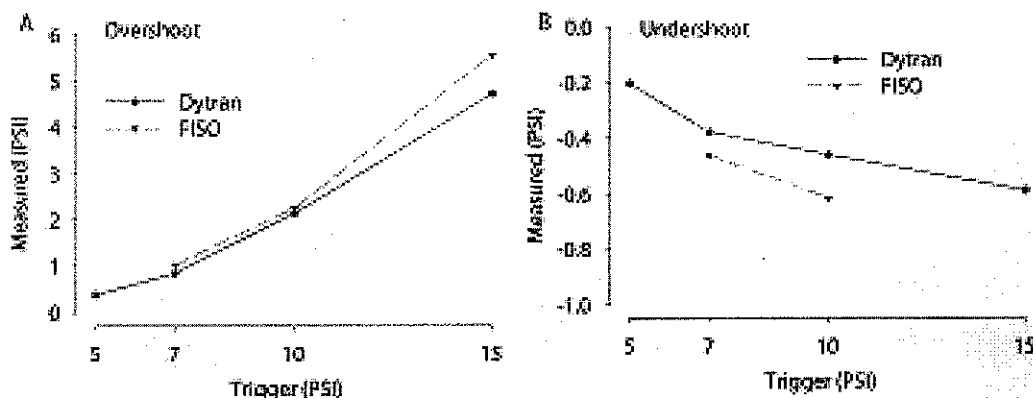


Figure 12: Summary of blast events recorded. Panel A: Maximum peak pressures recorded with both sensors. Panel B: Minimum peak pressures recorded with both sensors. The missing points for FISO sensors were not recorded during blast event. There was no significant ($p=0.533$) difference observed between both sensors recorded pressure measurements.

4.2 EAC pressure profile in cadaveric specimens:

Peak pressure within the ear canal was approximately 1.19 psi with the blast wave impinging laterally and 0.49 psi with the blast wave impinging frontally. Figure 13 shows the pressure

profiles as measured in the EAC during blast events and figure 14 shows the frequency spectrum. Figure 15 shows the EAC pressure profile during a blast event approaching frontally. The pressure measurement recorded here shows a lower signal to noise ratio, possible caused by mechanical movement of the sensors.

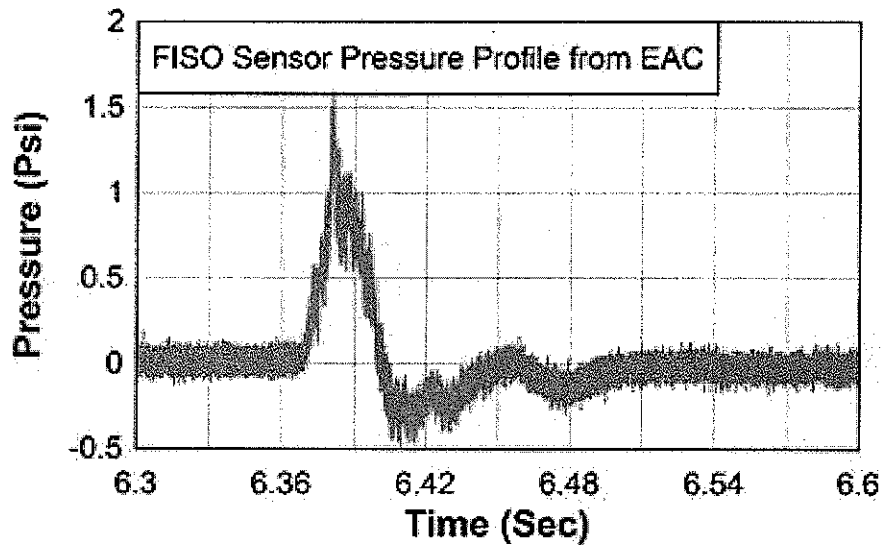


Figure 13: Pressure profile recorded at EAC.

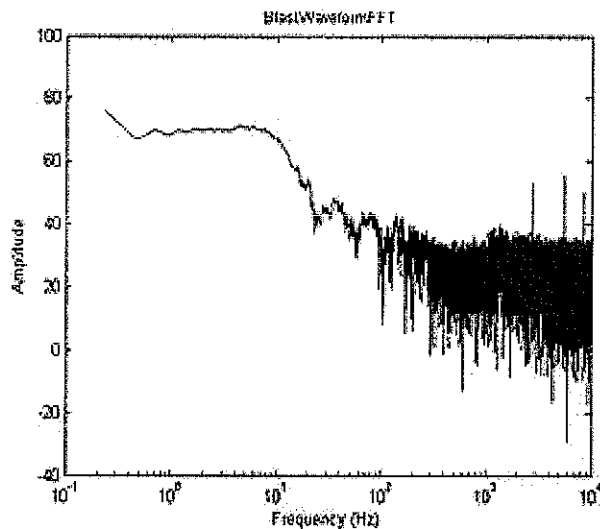


Figure 14: Frequency spectrum showing most of the energy at low frequencies around 10-20 Hz for EAC pressure profile.

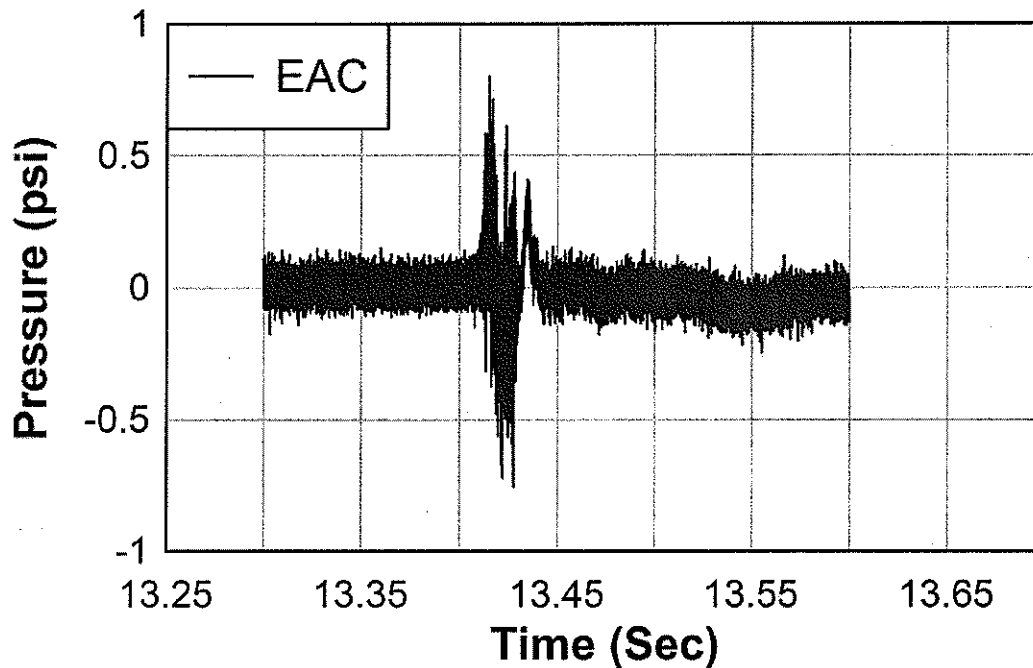


Figure 15: Cadaveric specimen pressures from EAC while blast event approaching frontally.

4.2.1 “Eddi” acoustic manikin head model pressure profiles:

Figure 16 shows the two pressure profiles (dynamic and static) recorded with fiber optic probes while the “Eddi” acoustic manikin was exposed to a lateral blast event. There is no significant difference observed between the two profiles. The peak values observed were similar, with 1.3945 for dynamic and 1.3961 for static pressures. Figure 17 shows the two pressure profiles (dynamic and static) recorded with fiber optic probes while “Eddi” acoustic manikin was exposed to a frontal blast event. There is no significant difference observed between the two profiles. The peak values observed were similar with 1.0421 for dynamic and 1.0465 for static pressures. There is a decrease in peak pressure from frontal to lateral blast impinging event.

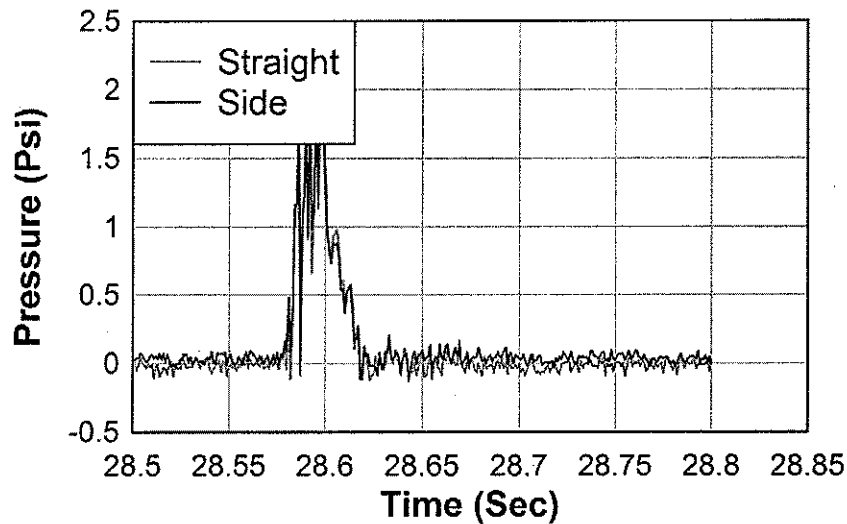


Figure 16: Pressure profile recorded with fiber optic probes on “Eddi” acoustic manikin head while it was exposed to a blast impinging laterally.

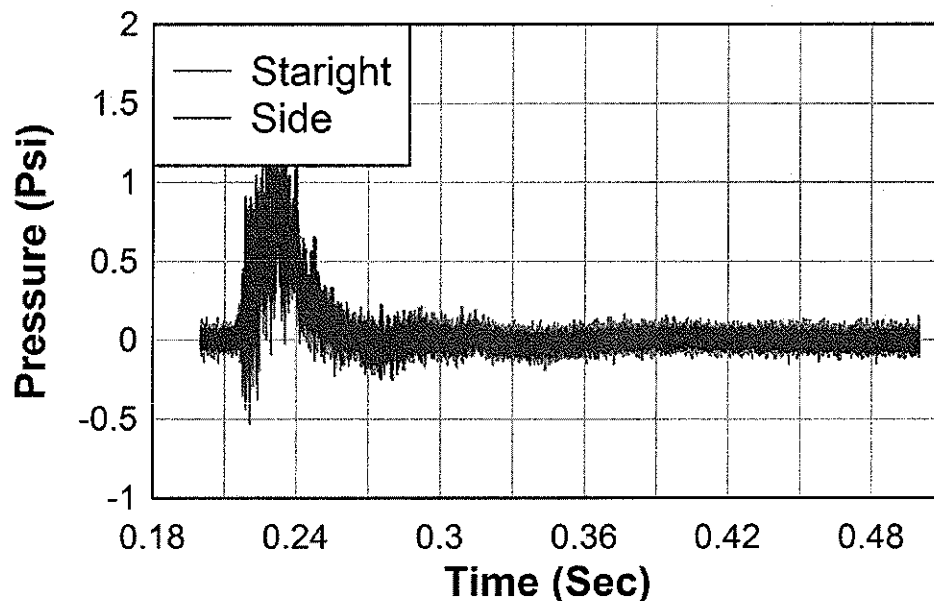


Figure 17: Pressure profile recorded with fiber optic probes on “Eddi” acoustic manikin head while it was exposed to blast even frontally.

4.3 Ossicular motions recorded with scanning LDV in Frequency Domain:

Ossicular displacements were processed in the frequency domain and peak displacements at different frequencies for either impulse or harmonic stimuli were extracted. The sound levels at

each corresponding frequency were also extracted from a reference microphone placed at the TM. The peak displacements across temporal bones were averaged for different stimulus levels. The peak displacements were shown for each ossicular structure in panels A of figures 18-19. The linearity in peak displacements was observed from increasing stimulus level from 100 dB SPL to 120 dB SPL. The peak displacement due to blast impulse which can be seen at 22 Hz was higher than the harmonic stimulus at other frequencies. The linear curve fittings were performed relating stimulus level to peak displacement for each ossicular structure (shown in corresponding B panels). The r^2 values were varied between 0.1 and 0.84 with a mean and STD of 0.475 and 0.172 respectively. The curve fitting functions were shown in panel B of figures from 5-9. The slight increase in slope of linear functions was observed across different frequencies (81, 250, 431, 613 and 1300 Hz) for harmonic stimulus and slope is significantly higher for impulse function which can be seen at 22 Hz. The displacements measured with harmonic stimuli from RW were similar to the data shown in figure 3 of Asai et al., 1999. The phase differences were also studied between different ossicular structures at different frequencies. There was no significant difference ($p>0.05$) in phase observed between Malleus head and Incus body; stapes and Incus long process. There was significant difference ($p<0.05$) observed between stapes and RW, for which the phase difference was close to the expected 180 deg.

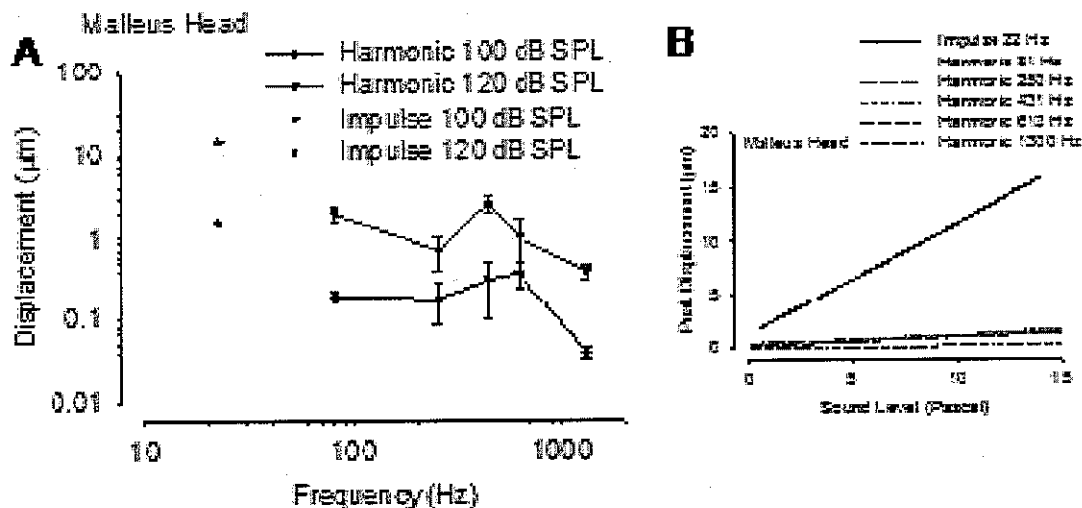


Figure 18A: Malleus head peak displacements are shown across temporal bones for different frequencies for 100 and 120 dB SPL. Figure 18B: The linear fittings of peak displacement at any particular frequency versus sound level in pascal.

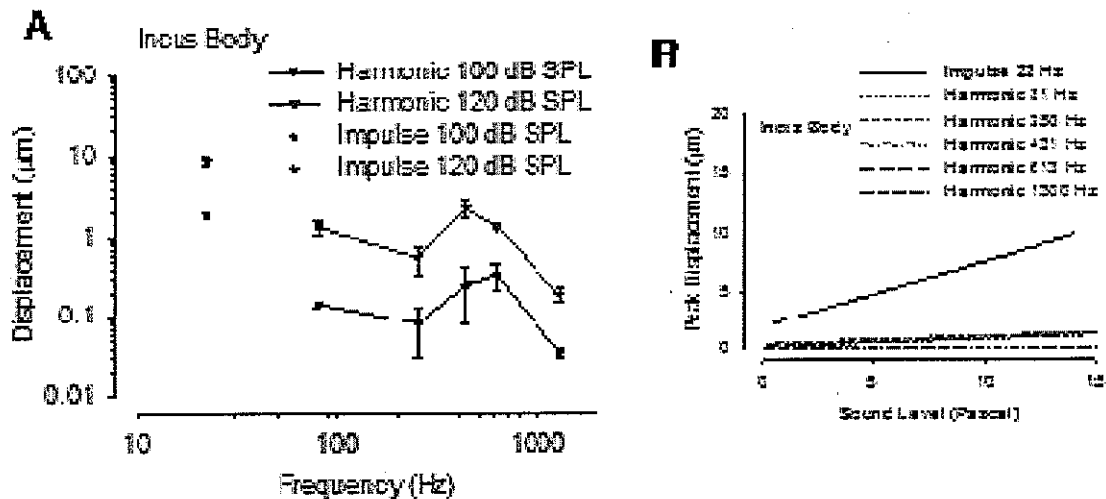


Figure 19A: Incus body peak displacements are shown across temporal bones for different frequencies for 100 and 120 dB SPL. Figure 19B: The linear fittings of peak displacement at any particular frequency versus sound level in pascal.

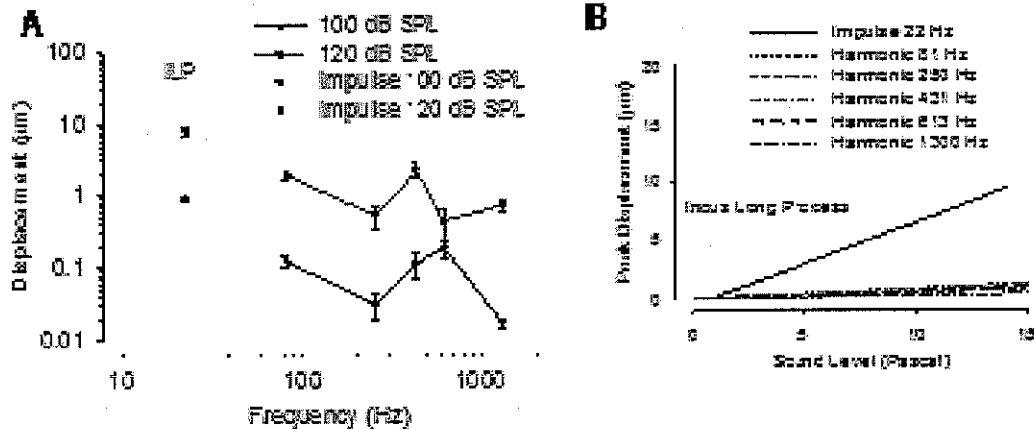


Figure 20A: Incus long process peak displacements are shown across temporal bones for different frequencies for 100 and 120 dB SPL. Figure 20B: The linear fittings of peak displacement at any particular frequency versus sound level in pascal.

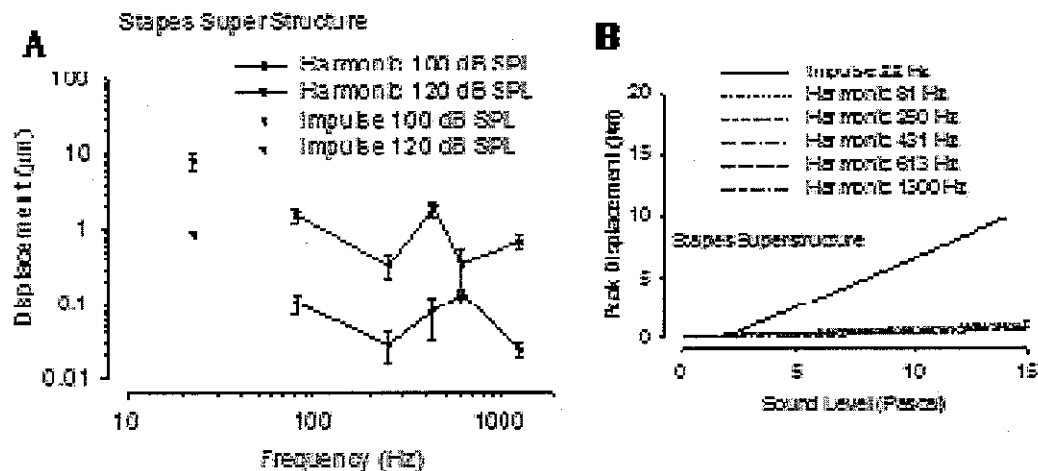


Figure 21A: Stapes peak displacements are shown across temporal bones for different frequencies for 100 and 120 dB SPL. Figure 21B: The linear fittings of peak displacement at any particular frequency versus sound level in pascal.

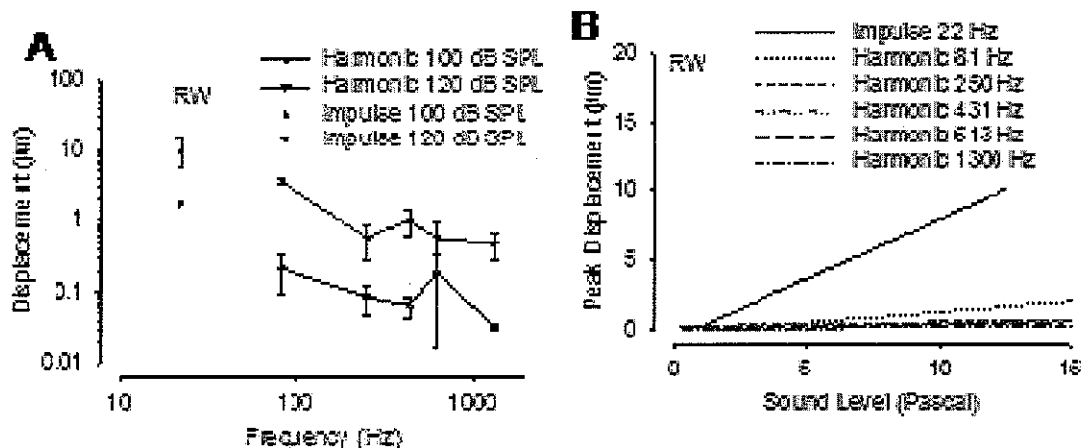


Figure 22A: Round window peak displacements are shown across temporal bones for different frequencies for 100 and 120 dB SPL. Figure 22B: The linear fittings of peak displacement at any particular frequency versus sound level in pascal.

4.4 Verification of current auditory injury models such as AHAH with present data:

The stimulus waveforms recorded with reference microphone at TM were presented to AHAH auditory damage prediction model. The peak stapes displacements and auditory risk units (A.R.U.) were noted for each stimulus waveform and for each temporal bone. Figure 23 shows the peak stapes displacements estimated from AHAH model and compared with measured peak stapes displacements from scanning LDV data and shown in panel A for harmonic and panel B for impulse stimuli. There was a significant difference ($p < 0.05$) between scanning LDV recorded displacements and those predicted by the AHAH model.

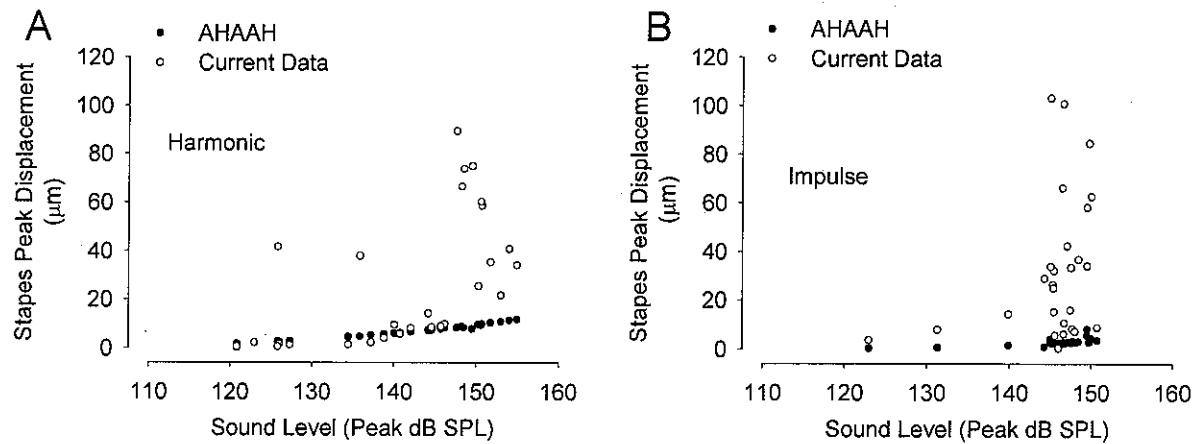


Figure 23A: Harmonic stimulus peak stapes displacement comparison of current scanning LDV data and AHAH model prediction. Figure 23B: Impulse stimulus peak stapes displacement comparison of current scanning LDV data and AHAH model prediction.

4.4.1 Auditory risk units (A.R.U.) prediction from AHAH model:

The ARU predicted from AHAH model for harmonic and impulse stimulus were compared and shown in figure 24. There was a significant ($p < 0.05$) difference between harmonic and impulse stimulation, with harmonic stimulation generating higher ARU values.

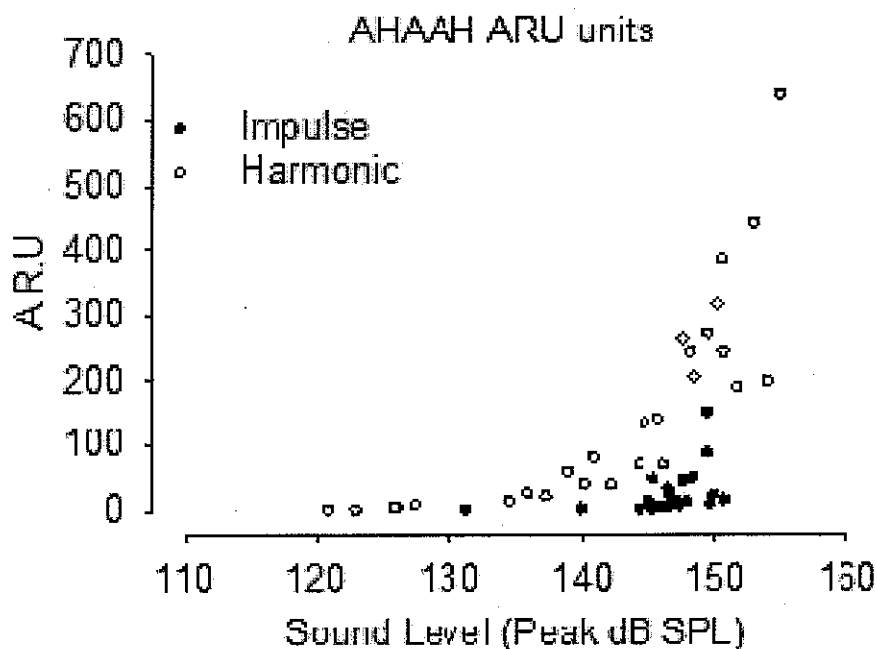


Figure 24: Auditory risk analysis predicted ARU units for harmonic and impulse response.

4.5 ARA Blast Chamber Calibration and Effect of Protective Equipment:

Figure 25 shows the blast wave form generated by a blast event at the ARA blast chamber. The blast event shown was recorded from the right ear canal near (~ 1 mm) the TM using Endevco and FISO sensors. The data shows good correlation between sensors. Figure 26 shows the blast event recorded without and with ear muffs. The ear muffs decreased the peak pressures from 13.2 PSI to 1.1 PSI in the example shown (attenuation of approximately 25-30 dB SPL). The ear muffs also helped in reducing the ear canal resonance which can be seen as ringing around 3 kHz for the dummy head models. Figure 27 shows the effect of protective equipment on peak pressures recorded in right and left ear canals. The ear muffs decreased the sound pressure levels by around 25-30 dB which can be observed from first point to second (comparison between Front None to Front Muffs condition). Ipsilateral (in-line) presentation of the blast overpressure to the EAC produced higher peak pressures within the EAC than frontal presentation of the BOP. The helmet did not decrease the peak pressures (which can be noticed at Front Helmet condition to Front None) at the ear canal as it was not covering the whole ear as ear muffs do.

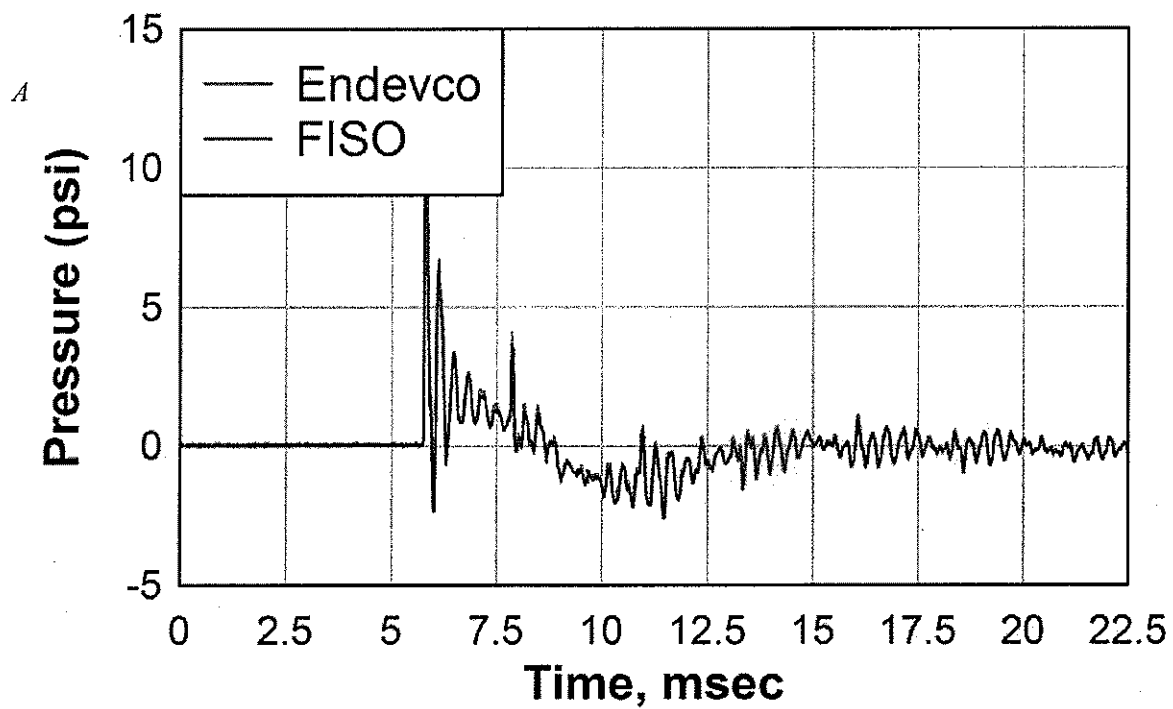


Figure 25: The blast event recorded at ARA blast chamber using two different sensors.

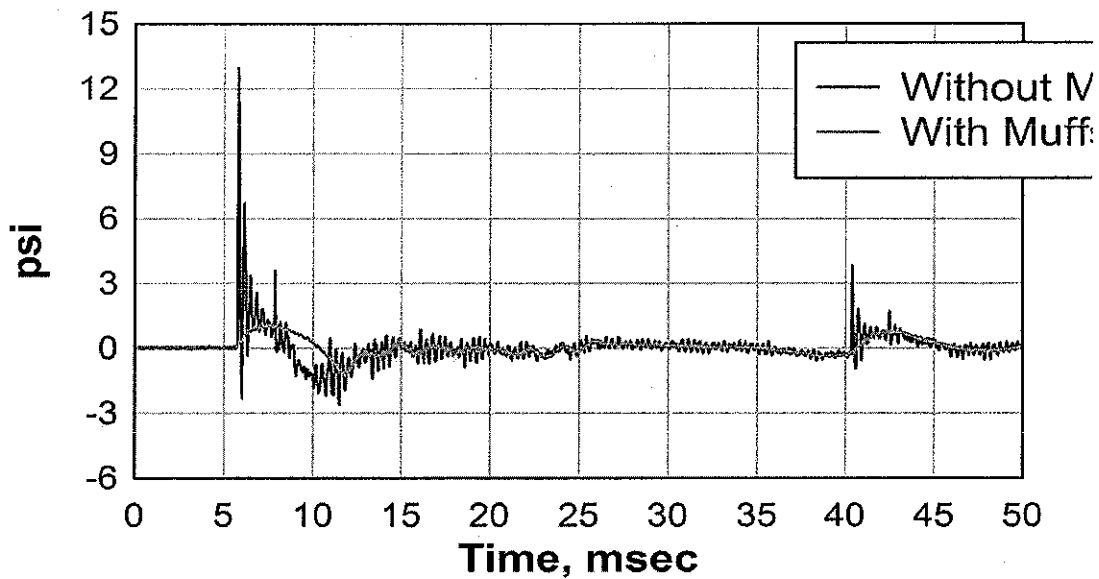


Figure 26: The application of ear muffs and decrease in peak pressures recorded at TM.

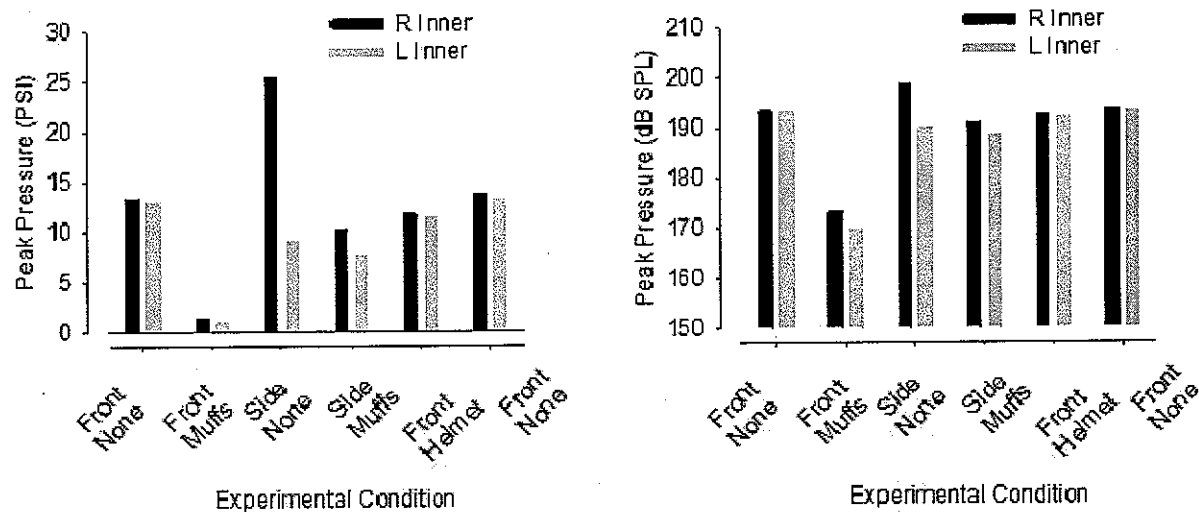


Figure 27: Peak pressures recorded at different conditions. Left panel shows the pressures in psi units and right panel shows in dB SPL units.

4.6 Ossicular Displacement at Low Frequencies (<100 Hz) at High Sound Pressure Levels:

The velocity response of the incus long process and incus body were measured in two temporal bones, and the velocities were converted to displacements. Figure 28 shows the ILP (top panels) and incus body (bottom panels) for two temporal bones measured. The displacements measured at 120 dB SPL for ILP and Incus body were similar to the scanning LDV data shown in figures 19 and 20 (at frequencies 250, 431, 613, and 1300 Hz). The displacements were around 1 μm range for 120 dB SPL as can be seen in figures 19-20 or current figure 28. The displacements at tones from 22 Hz to 1300 Hz increased linearly to 130 dB SPL. Above 130 dB SPL, the limitations of the LDV were reached and the amplitude of the displacements exceeded the recording capacity of the instrument. The experiment successfully demonstrated the ability of the present configuration of the bench top blast simulator to exceed 140 dB SPL output in the extreme low frequencies. Figures 29 and 30 show samples of unsaturated and saturated signals at 100 and ~140 dB SPL for microphone (Brüel and Kjær Type 4182, Norcross, Ga., USA) and HLV LDV signals.

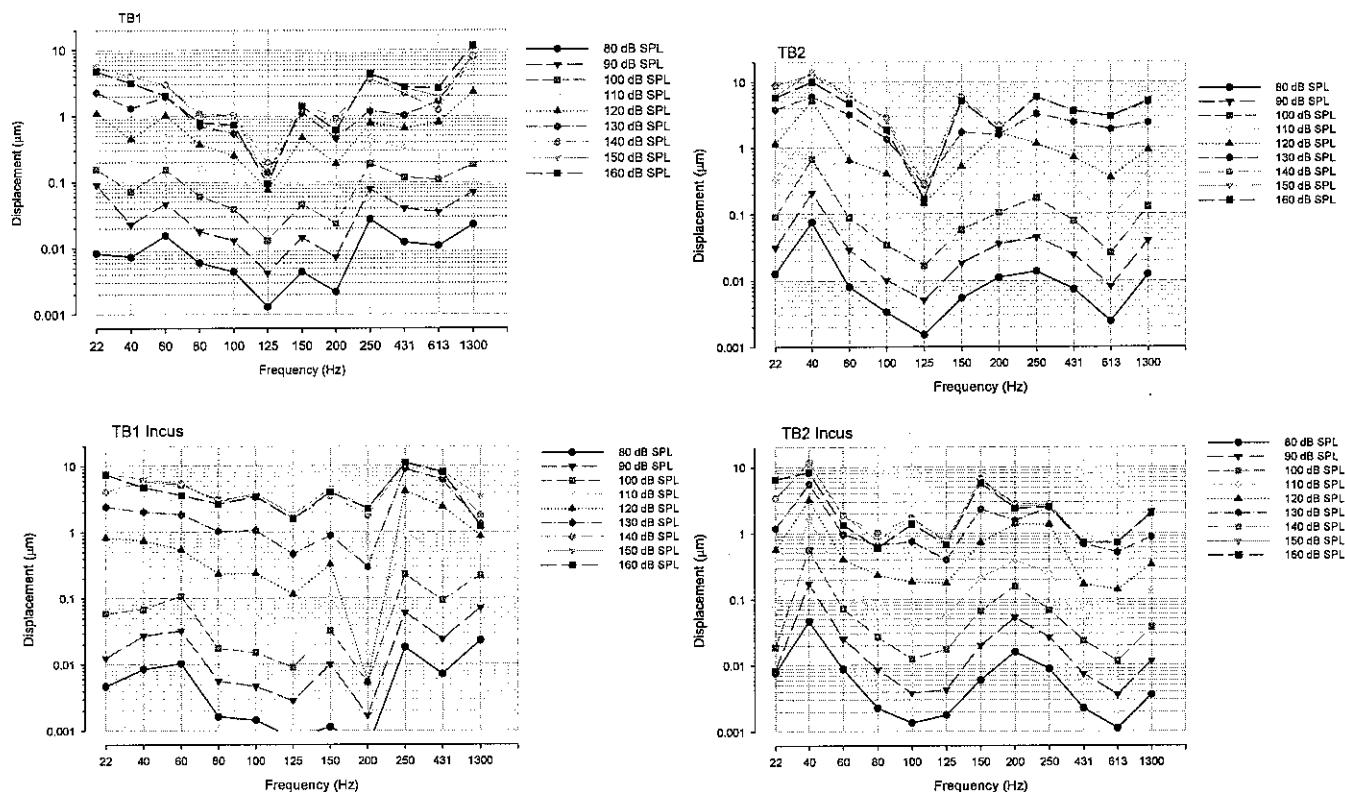


Figure 28: ILp and Incus body displacements measured with tones presented from 80 to 160 dB SPL at 10 dB steps. The displacements measured at higher dB SPLs above 140 are saturated due to limitation of HLV 1000 LDV.

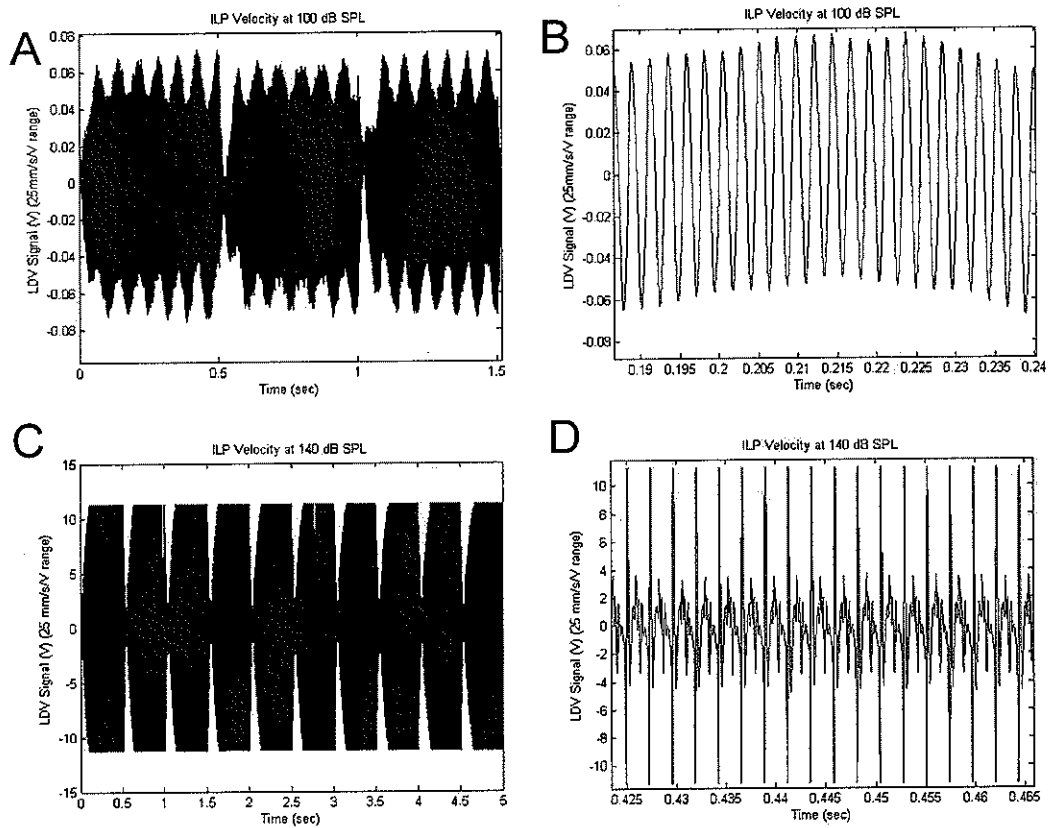


Figure 29: ILP velocity signals recorded with HLV 1000 LDV at 100 (panels A and B) and 140 (panels C and D) dB SPL sound pressure levels at TM.

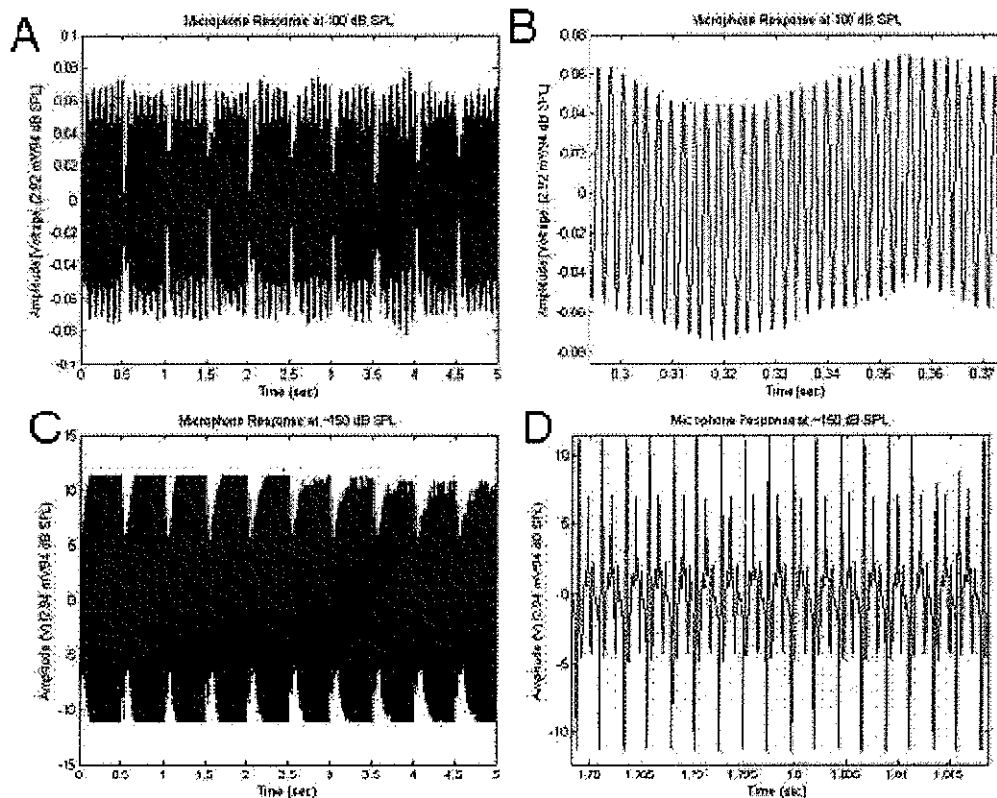


Figure 30: B&K Microphone signals recorded at TM for 100(panels A and B) and ~150 (panels (C and D) dB SPL.

5 KEY RESEARCH ACCOMPLISHMENTS

- Blast tube setup and calibration with fiber optic pressure sensors
 - Application of Fiber optic sensors for blast research applications
- Correlation of EAC/Intracranial whole head specimens
 - Measurement of pressure profiles across EAC and correlation with middle ear and intracranial measurements
- Effect of personal protective equipment
 - Application of protective equipment and decrease in auditory injury
- Bench top blast simulator setup
 - A compact, portable system to deliver high-intensity impulse to temporal bones
 - Stable and repeatable impulse or harmonic stimuli
 - A programmable model to simulate various conditions of interest
- Measurement of ossicular motion with scanning LDV
 - Simultaneous, real-time measurements of all three auditory ossicles
 - Recording of complex in-plane motion
 - Measurements at high sound pressure levels
- 1

- Comparison of measured ossicular motion with a predictive auditory injury model
 - Higher displacements than predicted by AHAH at high pressures and durations
 - Differences observed between harmonic and impulse response
- Modification of blast simulator for high intensity levels at low frequencies
 - Very high (>155 dB SPL) equivalent pressures
 - Stable high pressure sound pressure levels at frequencies below 100 Hz
- Measurement of ossicular motions at low frequencies (below 100 Hz) and very high sound pressure levels

6 REPORTABLE OUTCOMES

6.1 Oral presentation at ATACCC 2011

Measurement of Ossicular Motion due Simulated Blast Impulse and Chirp Signals: A Temporal Bone Study

Seven human cadaveric temporal bones were studied. The temporal bones were prepared with mastoidectomy and facial recess to view the malleus, incus body, incus long process, stapes and round window. A custom built speaker and condenser tube used to present stimuli of either pseudo blast pulse or chirp signals. Calibrated closed field stimuli were presented from 85 to 155 dB SPL. The scanning LDV was used to scan the total ossicular motion. The ossicular displacement was analyzed in frequency domain. The peak displacements were converted dB re: 1 μm . The observed peak displacements for malleus, incus body, incus long process, stapes and round window were as 12.3, 10.3, 9.4, 9.5, and 16.1 dB for 145 dB SPL for pseudo blast stimuli at 22 Hz and -3, -4, -4.7, -5, and 3 dB for 145 dB SPL blast impulse stimuli at 250 Hz. The phase difference between stapes and round window was observed as 180°. The blast impulse caused higher peak displacement compared to chirp stimuli at same dB SPL. The ossicular motion increased with increasing either blast impulse or chirp signals intensity. The ossicular displacements observed with chirp stimuli were varying linearly with stimulus level and exponential increasing with pseudo blast impulse stimulus tested. The peak displacements and phase velocities observed in current study will be used for simulation blast models.

6.2 Poster presentation selection for ARO 2012 Conference

Blast Wave Impact on Auditory Pathway: A Cadaveric Temporal Bone Study

The objective of the current study was to examine ossicular motion in response to simulated blast wave and harmonic stimuli in a temporal bone model. Seven human cadaveric temporal bones were prepared by mastoidectomy and extended facial recess exposing the malleus head (M), incus body (I), incus long process (ILP), stapes superstructure (S) and round window membrane (RWM). A custom built speaker and condensing tube were used to present harmonic stimuli from 100 Hz to 6000 Hz and a simulated blast overpressure waveform. Calibrated stimuli were presented from 85 dB SPL (0.000051 psi) to 135 dB SPL (0.0163). A scanning LDV was used to obtain simultaneous real-time images of the ossicles and round window membrane during harmonic and blast wave stimulation. Ossicular displacement was analyzed in the frequency domain. The peak displacements were averaged across bones; mean and standard errors were presented.

The phase difference between stapes and round window was observed to be approximately 180°. The observed out-of-plane peak displacements for harmonic stimuli at 110 Hz and above, and the variation of displacement with frequency, were similar to those reported in the literature. For a single impulse with over- and under-pressure simulating the Friedlander waveform characteristic of blast, the peak ossicular displacements were seen to be significantly (paired t-test, $p < 0.01$) higher than for harmonic stimuli with equivalent peak pressure, and greater than predicted by a widely used acoustic damage model. These results suggest that the response of the auditory system to high intensity, long-duration impulse may not be fully captured by existing models. The displacements and phase relationships observed under these conditions will be used to refine models of acoustic trauma from blast.

7 CONCLUSIONS

1. Ossicular displacements above 140 dB SPL are substantially greater than predicted by AHAH model. Impulse type stimuli generate higher peak displacements when compared to equivalent harmonic stimuli.
2. Mitigation of ossicular displacements secondary to blast and intense harmonic noise may be possible through loading/damping the ossicular chain without adverse impact on speech range auditory perception.
3. The ARA blast chamber has intensive capabilities to be used for this particular research.
4. The Ear muffs have shown some protection with decreased peak pressures.
5. The protective helmet did not decrease the pressures at ear canals as it doesn't cover the ear canals.
6. The modified cone in the bench top blast simulator event generator helped producing sound pressure levels up to 160 dB SPL or more.

The sound pressure levels above 160 dB SPLs need to be confirmed with FISO pressure sensors as regular B&K microphone saturates at those levels.

The displacements and velocities at higher sound pressure levels also need to be confirmed with an LDV with greater dynamic range (up to 1 m/s/V).

The future studies involve in depth understanding of mathematical models, how they predict the stapes displacement, and why predictions differed from current scanning LDV data.

The future studies will also include using Otologics LLC's MET stimulator to load on to ossicles and study the damping effect and best location of placement. Figure 31 shows the initial concept of method for damping ossicular displacement at high intensities with Otologics MET-V transducer loaded on to the ILP. The MET-V transducer can be used as hearing aid implant where indicated for conductive or sensorineural applications, and at the same time can be used to attenuate or totally block high intensity displacements due to a blast event.

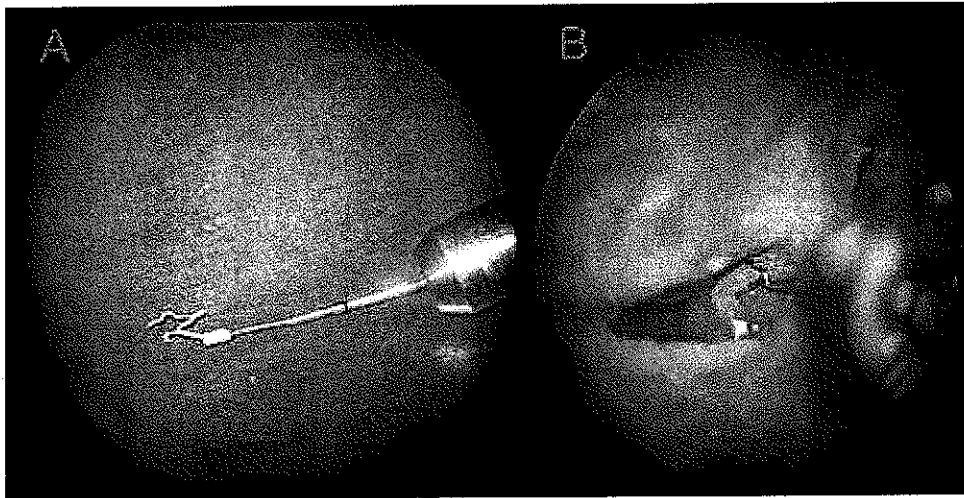


Figure 31: Panel A: Otologics' MET-V transducer tip with an a`Wengen clip attached at the end. Panel B: The MET-V is loaded on to the ILP in temporal bone.

8 REFERENCES

- Asai, M., Huber, a M., & Goode, R. L. (1999). Analysis of the best site on the stapes footplate for ossicular chain reconstruction. *Acta oto-laryngologica*, 119(3), 356-61.
- Tringali, S., Koka, K., Deveze, A., Holland, N. J., Jenkins, H. a, & Tollin, D. J. (2010). Round window membrane implantation with an active middle ear implant: a study of the effects on the performance of round window exposure and transducer tip diameter in human cadaveric temporal bones. *Audiology & neuro-otology*, 15(5), 291-302.
- <http://www.fiso.com/section.php?p=21>
- <http://www.tdt.com/products/MF1.htm>